REF 60-9552-0

DPP® HIV 1/2 Rapid Test Control Pack
Chembio HIV Reactive/Nonreactive Controls

Read this Product Insert and the DPP® HIV 1/2 Assay Product Insert completely before using this product. Follow the instructions carefully when performing the test as not doing so may result in inaccurate Test Results. Users of this test should follow the CDC Universal Precautions for prevention of transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other blood borne pathogens. [1]

STORAGE: Store at 2 to 8°C (36 to 46°F)

INTENDED USE
The Chembio HIV Reactive/Nonreactive Controls are quality control reagents for use with the Chembio DPP HIV 1/2 Assay only.

Run the Kit Controls under the following circumstances:
- **Each new operator prior to performing tests on patient specimens,**
- **When opening a new test Kit lot,**
- **Whenever a new shipment of test Kits is received,**
- **If the temperature of the test storage area falls outside of 2 to 30°C (36 to 86°F),**
- **If the temperature of the testing area falls outside of 18 to 30°C (64 to 86°F),**
- **At periodic intervals as indicated by the user facility.**

It is the responsibility of each laboratory using the DPP HIV 1/2 Assay to establish an adequate quality assurance program to ensure the performance of the device under its specific locations and conditions of use.

SUMMARY AND EXPLANATION OF HIV REACTIVE AND NONREACTIVE CONTROLS
Chembio HIV Reactive/Nonreactive Controls are human, plasma-based reagents. The Controls are specifically formulated and manufactured to ensure performance of the test, and are used to verify the user's ability to properly perform the test and interpret the results. The Chembio HIV 1 and HIV 2 Reactive Controls will produce a REACTIVE Test Result and have been manufactured to produce a faint Test "T" line. The Chembio Nonreactive Control will produce a NONREACTIVE Test Result. Use of Control Reagents manufactured by another source may not produce the required results, and therefore, will not meet the requirements for an adequate quality assurance program for the Chembio DPP HIV 1/2 Assay.

MATERIALS PROVIDED
Each HIV Rapid Test Control Pack contains a Product Insert and three Vials (one HIV 1 Reactive Control, one HIV 2 Reactive Control and one Nonreactive Control) as described.

HIV 1 Reactive Control
One Vial containing 0.5mL of heat inactivated human plasma positive for antibodies to HIV-1, diluted in normal human plasma. Negative for Hepatitis B surface antigen, Hepatitis C antibody and HTLV I/II antibodies.

HIV 2 Reactive Control
One Vial containing 0.5mL of heat inactivated human plasma positive for antibodies to HIV-2, diluted in normal human plasma. Negative for Hepatitis B surface antigen, Hepatitis C antibody and HTLV I/II antibodies.

Nonreactive Control
One Vial containing 0.5mL of normal human plasma negative for antibodies to HIV-1 and HIV-2. Negative for Hepatitis B surface antigen, Hepatitis C antibody and HTLV I/II antibodies.

MATERIALS REQUIRED AND PROVIDED in the Chembio DPP HIV 1/2 Assay

Each kit contains the items to perform 20 tests:
- 20 DPP HIV 1/2 Individually Pouched Test Devices
- 20 Disposable Sample Loops
- 20 DPP SampleTainer® Bottles (1mL) – BLACK Caps
- 20 Oral Fluid Swabs
- 1 DPP Running Buffer Bottle (6mL) – GREEN Cap
- 1 Product Insert

MATERIALS REQUIRED BUT NOT PROVIDED
- Clock, watch or other timing device
- Disposable gloves
- Biohazard disposal containers

WARNINGS
For *IN VITRO* diagnostic use
1. Read this Product Insert and the DPP Chembio HIV 1/2 Assay Product Insert completely before using this product. Follow the instructions carefully as not doing so may result in inaccurate Test Results.
2. Users of this test should follow the CDC Universal Precautions for prevention of transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other blood-borne pathogens.[1] And "Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposure to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis [2].
3. Handle the Chembio HIV Reactive/Nonreactive Controls, and materials contacting the Controls, as if capable of transmitting infectious agents.
4. Do not eat, drink or smoke in the area where specimens and kit reagents are handled. Avoid any contact with hands, eyes or mouth during specimen collection and testing.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when handling specimens.
6. Dispose of all specimens and materials used in the test procedure in a biohazard waste container. Lancets should be placed in a puncture-resistant container prior to disposal. The recommended method of disposal of biohazard waste is autoclaving for a minimum of 1 hour at 121ºC. Disposable materials may be incinerated. Liquid wastes may be mixed with appropriate chemical disinfectants. A freshly prepared solution of 10% bleach (0.5% solution of sodium hypochlorite) is recommended. Allow 60 minutes for effective decontamination.
   NOTE: Do not autoclave solutions that contain bleach.
7. Use 10% bleach or other appropriate disinfectant to wipe all spills. The bleach solution should be made fresh each day.
8. Use of Kit Control reagents manufactured by another source may not produce the required results, and therefore, will not meet the requirements for an adequate quality assurance program for the Chembio DPP HIV 1/2 Assay.

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STORAGE AND STABILITY

The Chembio HIV Reactive/Nonreactive Controls should be stored at 2 to 8°C (36 to 46°F). Do not use beyond the indicated expiration date. Open the Control Vials only when you are performing tests. Recap and store the Control Vials in their original container at 2 to 8°C (36 to 46°F) after use. The test devices should be stored in its unopened pouch at 2 to 30°C (36 to 86°F). Do not freeze. Do not open the pouch until you are ready to perform a test. When stored as indicated, Test Devices are stable until the expiration date marked on the pouch. Both Buffers (for Chembio DPP HIV 1/2 Assay) should also be stored at 2 to 30°C (36 to 86°F) in their original Vials.

TEST PROCEDURE

All components for the Chembio DPP HIV 1/2 Assay are ready to use as supplied. Instructions for use are given in the Chembio DPP HIV 1/2 Assay Product Insert. Follow directions as indicated. If the specimen to be tested is refrigerated, remove it from the refrigerator and allow it to come to a temperature of 18 to 30°C (64 to 86°F) prior to testing.

Procedure for Using Controls with Chembio DPP HIV 1/2 Assay

1. Open a Control Vial containing the Control Reagent.
2. Remove the Chembio DPP HIV 1/2 Assay Test Device from its pouch and place it on a flat surface (It is not necessary to remove the desiccant from the pouch).
3. Label the Test Device with Control Reagent name or identification number.
4. Note that the DPP test device has 2 colored lines in the Test Window; one is blue and the other is green. If the 2 colored lines are absent, DO NOT USE. Discard the test device and use a new test device.
5. Use a laboratory pipet to withdraw 10µL of the control sample.
6. Pipette the sample into the SampleTainer with the BLACK CAP, such that the pipette tip is touching the bottom of the bottle.
7. Dispense liquid. Replace the BLACK/WHITE CAP assembly onto the bottle and gently shake the bottle for 10 seconds.
8. Test immediately, following Test Procedure instructions.
    a. Invert the SampleTainer (BLACK CAP), containing the collected control material diluted in SampleTainer buffer, and hold it vertically (not at an angle) over the SAMPLE + BUFFER Well 1. Slowly add 2 drops (~65µL) into the SAMPLE + BUFFER Well 1.
    NOTE: The Control Reagents are clear to straw-colored. Do not use if the Control Reagent appears visually cloudy or discolored.
    b. Wait 5 minutes. The blue and green colored lines should have disappeared from the rectangular TEST and CONTROL window. If not, discard the test device and repeat the procedure with a new DPP test device.
    c. Invert the Running Buffer bottle (Green CAP), and hold it vertically (not at an angle) over BUFFER Well 2. Slowly add 4 drops (~135µL) of Running Buffer (GREEN CAP) to BUFFER Well 2.
    d. Read the test result 10 to 25 minutes after the addition of the Running Buffer to BUFFER Well 2. In some cases a test line may appear in less than 10 minutes however, 10 minutes are needed to report a nonreactive result. Read results in a well-lit area. Do not read results after 25 minutes from the addition of the Running Buffer to BUFFER Well 2.
9. Discard the used pipet tips, Test Device and any other test materials into a biohazard waste container.
10. Reseal the Control Reagent Vials and store them in their original container at 2 to 8°C (36 to 46°F).

QUALITY CONTROL

Built-in Control Feature

The control line serves as a built-in internal control and gives confirmation of sample addition and proper test performance. A pink/purple line will appear in the CONTROL area if the test has been performed correctly and the Device is working properly (Please see section: Interpretation of Test Results).

INTERPRETATION OF TEST RESULTS

Please refer to the DPP HIV 1/2 Assay Product Insert for pictorial examples of REACTIVE, NONREACTIVE and INVALID Test Results.

1. The **CONTROL LINE** - which appears adjacent to the result window labeled “C” indicates that specimen was adequately applied, and there was proper hydration and migration of reagents. The control line will become visible within 10 minutes after the addition of the Running Buffer to BUFFER Well 2 regardless of the HIV antibody status of the specimen.

2. The **TEST LINE** - which appears adjacent to the result window labeled “T” indicates the presence of HIV-specific antibodies. The test line will only become visible within 10 minutes after the addition of the Running Buffer to BUFFER Well 2 when HIV specific antibodies are present at detectable levels in the specimen.

3. **INVALID -** A pink/purple line should always appear in the CONTROL area, whether or not a line appears in the TEST area. If there is no distinct pink/purple line visible in the CONTROL area, then the test is INVALID. Any of the lines appear outside of the areas to the Control or Test is an INVALID test. An INVALID test cannot be interpreted. It is recommended that the test be repeated with a new Device.

EXPECTED RESULTS

Nonreactive Control:

The Nonreactive Control will produce a NONREACTIVE Test Result. A pink/purple CONTROL (C) line should be present adjacent to the result window labeled “C”. There should be no visible line in the Test (T) area of the Device. This indicates a NONREACTIVE Test Result.

HIV 1 Reactive Control:

The HIV 1 Reactive Control will produce a REACTIVE Test Result and has been manufactured to produce a faint pink/purple TEST (T) line. A line should be present adjacent to the result window labeled “T”. A pink/purple CONTROL (C) line should be present adjacent to the result window labeled “C”. This indicates a REACTIVE Test Result. The intensities of the TEST (T) and CONTROL (C) lines may vary. If any visible line appears in the TEST (T) and CONTROL (C) areas, the result is REACTIVE.

HIV 2 Reactive Control:

The HIV 2 Reactive Control will produce a REACTIVE Test Result and has been manufactured to produce a faint pink/purple TEST (T) line. A line should be present adjacent to the result window labeled “T”. A pink/purple CONTROL (C) line should be present adjacent to the result window labeled “C”. This indicates a REACTIVE Test Result. The intensities of the TEST (T) and CONTROL (C) lines may vary. If any visible line appears in the TEST (T) and CONTROL (C) areas, the result is REACTIVE.

NOTE: If the Test Result for the Nonreactive Control, HIV 1 Reactive Control, or HIV 2 Reactive Control is not as expected, the test should be repeated using a new Test Device and Control Specimen. If the HIV Control Reagents do not produce the expected results and you are unable to obtain a valid Test Result upon repeat testing contact Chembio Diagnostic Systems Customer Service at 1-631-924-1135 or Toll Free, at 1-800-327-3635.

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LIMITATIONS

The Chembio HIV Reactive/Nonreactive Controls are quality control reagents for use **ONLY** with Chembio DPP HIV 1/2 Assay.

REFERENCES

1. Centers for Disease Control and Prevention (CDC). Universal Precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings. MMWR 1988: 37(24):377-388.
2. Centers for Disease Control (CDC): Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis. MMWR 2005; 54(RR09): 1-17.

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ORDERING INFORMATION

REF 60-9552-0 DPP® HIV 1/2 Rapid Test Control Pack

AVAILABLE ACCESSORIES

REF 65-9500-0 Chembio DPP® HIV 1/2 Assay, 20 Tests

SYMBOL LEGEND

	CONSULT THE MANUAL BEFORE USE
	CAUTION, CONSULT ACCOMPANYING DOCUMENTS.
	DO NOT REUSE
	FOR USE WITHIN TEMPERATURE LIMITS
IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE
LOT	BATCH CODE
REF	PRODUCT CATALOG NUMBER
	MANUFACTURERS IDENTIFICATION
	DATE OF MANUFACTURE
	USE BY DATE